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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/412,085 | 10/04/1999 | JOSEPH MIZRAHI | 6786.141US01 | 9196 |

23552 7590 01/07/2002

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EXAMINER

PRATS, FRANCISCO CHANDLER

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1651

DATE MAILED: 01/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/412,085

Applicant(s)

MIZRAHI ET AL.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 13, 21, 24-30 and 32-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 13, 21, 24-30 and 32-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The request filed on November 13, 2001, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/412,085 is acceptable and a CPA has been established. An action on the CPA follows.

The amendment filed November 13, 2001, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim 31 has been cancelled.

Claims 1, 13, 21, 24-30 and 32-39 are pending and are examined on the merits.

Claim Rejections - 35 USC § 103

Claims 1, 13, 21, 24-30 and 32-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al (U.S. Pat. 4,771,001) in view of Lehnhardt et al (U.S. Pat. 5,426,219) for the reasons of record set forth at pages 4-7 of the office action of December 19, 2000.

All of applicant's argument has been fully considered but is not persuasive of error. It is noted that concentration of Bailey's initial lactic acid solution according to Lehnhardt's disclosure would require effort. However, it is generally

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recognized that economic unfeasibility does not negate obviousness. See MPEP § 2145, item VII. Moreover, Lehnhardt clearly provides a reason for concentrating the initial lactic acid solution, stating explicitly that concentrating the solutions provides the practitioner the advantage of using smaller volumes. See Lehnhardt at col. 4, lines 15-17.

("Further, working at higher concentrations of lactic acid reduces the volumes of and number of extraction stages. Thus, the present invention has advantages of simplicity, reduced cost, and reduced effluent compared to the prior art.") Thus, Lehnhardt clearly provided the artisan of ordinary skill practicing Bailey's process a reasonable expectation that concentrating the initial lactic acid solution would be advantageous and desirable.

It is noted that Bailey's extraction process, based on a pH gradient, is somewhat different than Lehnhardt's "salting out" type lactic acid extraction. It is also noted that concentration of the initial lactic acid solution is particularly suitable in Lehnhardt's extraction process, as the extraction solution must be substantially saturated with at least one electrolyte. However, the simple fact remains that the artisan of ordinary skill extracting lactic acid according to Bailey's disclosure clearly would have recognized from

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Lehnhardt that concentrating the initial lactic acid solution would have been advantageous even in Bailey's process. That is, despite the specific differences between the two processes, the advantages of higher lactic acid concentrations disclosed by Lehnhardt clearly would have been recognized by the artisan of ordinary skill to be applicable to Bailey's process.

As to the improvement in extraction efficiency argued by applicant as being presented in Figure 4, it is again noted that, on the current record it merely appears that if one concentrates the lactate solution before acidulation and extraction, one can obtain a more concentrated solution after extraction. It is again respectfully submitted that this result is expected. Moreover, while applicant asserts that the data presented in Figure 4 clearly represent a result unexpected by extrapolating the data below 12% initial lactic acid concentration, note specifically that in the presence of the sulfuric acid enhancer the slope of the curves above 12% are comparable or even lower (Example "C") than the slopes below 12%. Thus, it is respectfully submitted that the data are not as clear as urged by applicant.

As to the failure of the references to disclose the use of calcium lactate, note specifically that independent claim 1 only requires the solution to "include" calcium lactate. Thus, the

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claims encompass even miniscule amounts of calcium lactate. Bailey's fermentation medium, which contains calcium ion, would necessarily contain some calcium lactate. Bailey therefore meets the claims in this respect. Applicant's argument in this respect clearly does not reflect the actual language present in the claims.

Lastly, as to the failure of either of the references to disclose the presence of sulfuric acid in the amine extractant, as discussed on page 6 of the office action of December 19, 2000, the inclusion of sulfuric acid in the amine extractant of Bailey clearly would have been obvious in view of the fact that such a step would have been expected to have maintained the required acidic pH in the aqueous phase of the extraction milieu. As argued by applicant above, Bailey's extraction is based on a pH differential between the aqueous lactic acid solution and the organic amine extractant. By including acid in the extractant, the artisan of ordinary skill clearly would have been able to ensure the presence of the critical pH gradient. The rejection must therefore be maintained.

No claims are allowed.

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This is a CPA of applicant's earlier Application No. 09/412,085. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner

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can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Francisco C Prats
Primary Examiner
Art Unit 1651

FCP
January 4, 2002